ANTIBIOTIC CEMENT IMPREGNATED NAILING IN THE MANAGEMENT OF INFECTED NON UNION OF FEMUR AND TIBIA - A PROSPECTIVE STUDY

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CERTIFICATE

This is to certify that DR.A.SARAVANAN, post – graduate student (2008- 2010) in the Department of Orthpaedic Surgery, Government Kilpuak Medical College, Chennai has done dissertation on "**ANTIBIOTIC CEMENT IMPREGNATED NAILING IN THE MANAGEMENT OF INFECTED NON UNION OF FEMUR AND TIBIA - A PROSPECTIVE STUDY"** under my guidance and supervision in partial fulfillment of the regulation laid down by **THE TAMILNADU DR M.G.R MEDICAL UNIVERSITY, CHENNAI-600 032** for M.S (Orthopaedic Surgery) degree examination to be held on March 2010.

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DECLARATION

I, DR.A.SARAVANAN, solemnly, declare that dissertation titled **"ANTIBIOTIC CEMENT IMPREGNATED NAILING IN THE MANAGEMENT OF INFECTED NON UNION OF FEMUR AND TIBIA"** is a bona fide work done by me, at Government Kilpauk Medical College between 2008 - 2010, under the guidance and supervision of my respected unit chief **Prof.Dr.K.V. CHANDRASEKARAN, M.S. Ortho., D.Ortho.** This dissertation is submitted to THE TAMILNADU DR M.G.R MEDICAL UNIVERSITY, towards partial fulfillment of regulation for the award of M.S.DEGREE BRANCH-II in Orthopaedic Surgery.

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CONTENTS

Introduction

INTRODUCTION

Despite advances in antibiotics and operative treatment, infected nonunion remains difficult to treat, with considerable morbidity and health-care costs. The presence of poorly vascularized tissues, the adherence of bacteria to bone structures and implants and a slow bacterial replication rate all contribute to the persistence of the infection.

Nonunion in the presence of infection presents with the dual problems of controlling infection and providing stability. Various factors contribute to infected nonunions, including open fractures, infection after internal fixation, chronic osteomyelitis with pathological fractures, and surgical debridement of infected bone. Traditionally, the treatment strategy consists of surgical debridement with local and systemic antibiotic delivery and then a second procedure for stability, generally either internal or external fixation. Special reconstructive procedures and soft tissue procedures might also be necessary. Local antibiotic therapy is a useful technique that results in high local concentrations of antibiotics with minimal systemic levels and without systemic side effects. This method in the form of antibiotic-impregnated kuntscher nails is used in the treatment of osteomyelitis and in open fractures controls infection. With the goal of avoiding more than one procedure in these patients, we present our single-procedure technique of treatment with an Kuntscher nail coated with antibiotic-impregnated bone

cement, which combines local antibiotic delivery with good alignment and intramedullary fixation.

Infected nonunion has been defined as a state of failure of union for 6-8 months with persistent infection at the fracture site. The incidence seems to be increasing especially in view of increasing high velocity trauma, which is more frequently treated with internal fixation.

It is difficult to treat infected nonunion because of following reasons.

1. Previous surgeries would have resulted in scarring and fibrosis of the soft tissue with an avascular environment around the fracture site due to periosteal stripping.
2. The presence of dead bone or sequestrum at the fracture site prevents union.
3. Thrombosis of blood vessels of Haversian canals leading to non-viable bone at fracture site leading to nonunion.
4. Non weight-bearing, prolonged immobilization, multiple surgeries with fibrosis of the muscles leading on to a stiff joint / fracture disease.
5. Resistance to the systemic antibiotic therapy poses a problem in controlling the infection and achieving union.

Absence of skin cover, scar with multiple sinuses, osteomyelitis, osteoporosis, systemic antibiotic resistance all complicates treatment and

rehabilitation. Presence of scarring and fibrosis prevents adequate delivery of antibiotics even when maximum intravenous dose is given. These factors make an unfavourable milieu for fracture union. Even after prolonged treatment and repeated surgeries the outcome is still unsure. Bony union is not usually obtained until the infection has been controlled.

Three entirely different methods of treatment have been recommended for this difficult problem in the past. These include the conventional or classic, active or modern and treatment by pulsed electromagnetic fields. The major disadvantages of these procedures being multiple surgeries, need of an external fixator for stabilisation, and associated poor compliance.

The current management of this kind of infection consists of two main objectives. Infection control which is usually achieved by implant removal with debridement, lavage of medullary canal and fracture stabilization, which usually is accomplished by alternative fixation mostly external fixation. Kuntscher's intramedullary nailing has been used for fixation of a variety of fracture including those of the tibia. Although this device does not have the advantage of locking, it's place in the armamentarium of fixation of the femur and tibial fracture is undisputed specially because it allows vertical compression and is the most economic options amongst all the intramedullary implants.

Aim of the study

AIM

- To discuss the biological advantage of antibiotic cement impregnated nailing in the management of infected nonunion of femur and tibia.

- To evaluate the clinical outcome of infected nonunion of femur and tibia managed by antibiotic cement impregnated kuntscher nail.

Review of Literature

REVIEW OF LITERATURE

1. **Chirurgie de la main vol 26, Issues 4-5 Aug-Oct 2007, page 243-246. Institute of orthopaedics and traumatology Prof. Dr.CarlosE. Otto lenghi "Hospital Italiano Buenos Aires.**

   Study : Infected non-union of humerus treated with an antibiotic cement rod. Case report : the authors present a case of an infected nonunion of humerus treated initially with reaming of the medullary canal followed by the introduction of an antibiotic impregnated IM rod. Reconstruction of humerus with bone graft was done at second stage. The final results were healing of the fracture and a good functional result with no evidence of recurrence of infection at a 25 months follow up.

2. **NaG KH, Park SJ, *Ban* SK, Sung HS, ChoiiNY, Department of orthopaedic surgery, St Paul's hospital, The Catholic University of Korea, college of Medibine, Seoul, Korea. J. Korean Fracture SOC 2003, Oct 16: (4): 511-518**. Study: Treatment of infected non-union of long Bones: Comparison between fixation by antibiotic cement loaded IM nailing and fixation by antibiotic cement loaded external fixator. Among the 15 case of infected non-union of long bone shaft, 6 cases treated with fixation by antibiotic cement coated IM nailing and 3 cases treated with fixation by IM nailing along with antibiotic cement beads insertion were divided as group I (n=9) and other 6 cases treated with fixation by external fixator along with

antibiotic cement beads (insertion were divided as group II (n=6).

Conclusion : In the treatment of infected non - union of long bones with mild bone loss and shortening of less than 1 cm, the fixation by IM nailing with use of antibiotic cement is preferred to external fixator. With use of antibiotic nail union, control of infection and clinical aspects such as alignment, early ambulation and joint stiffness are better.

3. **Gianluca Giavaresi Velonica Borsari, Milena Fini, Roberto Giardeno, Vitlorio sambri, Paolo Gaibani, Revizo soffiatti J orthop Res. : 2008 Jan 9.** Study: Preliminary investigations for new gentamicin and vancomycin coated PMMA nail for the treatment of bone IM infections an experimental study in rabbits.

To evaluate a new gentamicin - vancomycin impregnated (2:1) PMMA coated nail drug delivery device to treat bone and IM infected MRSA was used to induce femoral osteomyelitis in 20 Newzealand male rabbits. 4 weeks after inoculum, the animals were submitted to debridement of infected femoral canal.

Group I : Insertion of a steel IM nail

Group II : Insertion of GM vancomycin impregnated PMMA Nail

Group III : No therapy

Group IV : No fixation, 1 week systemic antibiotic therapy with teicoplanin IM. At 7 weeks after inoculum the radiological score showed that the lowest

and best cure was obtained in Group II.

4. **Susan M. Rapp orthopaedics Today 2008, 28: 24**

Study : Antibiotic coated rods treated infection, stabilize defects.

In 2002, conway devised the technique. 32 cases were studied with silicone tubing with an inner diameter of 12.5 mm or less with cement, places the rod inside, lets the cement set and then cuts away the tubing.

Cultures showed most patients had MRSA. Mixing 3.6 gm of Tobramycin and 1 gm of vancomycin into a 40 gm package of bone cement. Conway found nails coated in antibiotic cement were an effective treatment with a 73.1% success rate.

5. **Zhang Qiang, Pan Zhijun, Xu Jian Jie, Littang, Li Jian birg, and Li Fang cae. Archieves of orthopaedic and Trauma surgery volume 127, Dec 2007**. Study: 19 infected patients underwent removal of the nails, excision of sinus tract, debridement of the canal and insertion of the rods. No recurrent infection occurred, 11 cases achieved bony healing, 6 cases showed partial union. We conclude that antibiotic cement rods could be a relatively effective, simple and inexpensive method of treating intramedullary infections after nailing.

6. **Han SK, NT,, Park SJ, Lee SK, Jang G, Lee IJ, J. Korean orthop Assoc 2000 Oct 35 (5): 699-703, Korean**. Study : Our study was again to evaluate the results of treatment of antibiotic cement coated unreamed

nailing for infected non-union of long bones 10 cases, 6 femurs and 4 tibia were included in our study. All of the 10 cases had bony union. Union time was average 31.5 weeks in femur and 26.4 in tibia. Early weight bearing ambulation and motion of adjacent joint were beneficial.

7. **Thonse R. Conway J. Musgrove Park Hospital, Belfast ; United Kingdom. Journal of orthopaedic Trauma 2007 Apr 21(4) : 258 – 68. Study** : Chronic infection of bone with non union is traditionally treated by a 2 stage procedure involving initial debridement and antibiotic delivery and then definitive internal fixation. A technique with antibiotic cement coated. Interlocking nails are prepared in operating room with the use of nails and materials that generally are available is here in described. This technique was used in a series of 20 patients. In 17 patients, the goal of bony union was achieved (85%). In the remaining 3 patients (15%) the goal of control of infection was achieved with stable non union (1 patient) and stable non-union with cement spacer (2 patients) 4 patients (20%) experienced cement nail debinding during removal.

8. **Qiang Z, Jun PZ, Jie XJ, Hang L, Bing LJ, Cai LF. Arch Orthop. Trauma Surg. 2007, Dec ; 127 (10); 945-51. E Pub 2007, Mar 27**. **Study** Use of antibiotic cement rod to treat intramedullary infection after nailing preliminary study in 19 patients. We use self made antibiotic cement rod to treat intramedullary infections. Compared with the beads it provides some

limited mechanical support and can be preserved in the canal for a long time. We reviewed 19 infected patients who underwent removal of the nail excision of sinus tracks, debridement of the canal and insertion of the rods. No recurrent infection occurred in 18 cases, 11 cases achieved bony union, 6 cases achieved partial union. 1 patient had non - union and 1 patient underwent amputation because of severe primary trauma and long term infection. The rod was removed between 35 and 123 days after implantation we conclude that the antibiotic cement rod could be a relatively effective, simple and inexpensive method of treating IM infectious after nailing.

Causes of Nonunion

CAUSES OF NONUNION

In 1986 Food and drug administration (orthopedic advisory panel) defined Nonunion as "established when a minimum of nine months have elapsed since injury and the fracture shows no visible progressive signs of healing for 3 months". But that criterion cannot be applied to every fracture. A fracture of shaft of long bones should not be considered as non-union until at least 6 months after the injury, because often union requires more time, especially after some local complications such as an infection.

"The designation of nonunion is currently made when the surgeon believes the fracture has little or no potential to heal." Donald Wiss M.D. & William Stetson M.D. Journal American and Orthopedic Surgery 1996.

Non union can result from the following causes

LOCAL FACTORS

1) Infection

Bone death (sequestrum)

Osteolysis (Gap)

"Of all prognostic factors in tibia fracture care, that implying the worst prognosis was infection" Nicoll E.A. CORR 1974.

2) Loosening of implants

3) Energy of fracture mechanism

4) Initial Fracture Displacement

Delayed union and nonunion were nearly three times as frequent in tibia fractures with moderate to severe displacement as compared to fractures with mild displacement.

5) Mechanical factors of fracture configuration

   Fracture patterns in higher energy injuries (i.e.: comminution, bone loss, or segmental patterns) have a higher degree of soft tissue and bone ischemia

6) Increased motion between fracture fragments

7) Inadequate fixation

8) Wolf's Law - lack of physiologic stresses to bone

9) Anatomic location

10) Inadequate immobilization

11) Gap between fragments

   a) Soft tissue interposition

   b) Malposition or over riding or displacement of fragments

   c) Loss of bone substance

   d) Distraction by hardware or traction.

12) Loss of blood supply

   a) Damage to nutrient vessel

   b) Excessive stripping or injury to periosteum and muscles.

Incidence of nonunion is increased with open fractures. More severe open fracture (i.e. Gustillo III B vs Grade I) have higher incidence of nonunion.

Soft tissue disruption: 1. Iatrogenic 2. Traumatic

SYSTEMIC FACTORS

Age, nutrition, steroids, radiation, anticoagulants, DM, immunodeficient states etc.

1) Malnutrition

Adequate protein and energy is required for wound healing

Screening test : serum albumin, total lymphocyte count

Albumin less than 3.5gm/dl and lymphocytes less than 1,500 cells/ml is significant **. Campbell 11th edition**.

2) Smoking

Decreases peripheral oxygen tension

Dampens peripheral blood flow

Well documented difficulties in wound healing in patients who smoke**. Schmite, M.A. e.t. al. CORR 1999. Jensen J.A. e.t. al. Arch Surg 1991**.

Causes of Nonunion

CLASSIFICATIONS OF NONUNION

There are various classifications available for non-union and infected non-union in the literature.

I - **Judet, Muller, Weber and Cech** classified non-union broadly into two types. They are

a) Hypertrophic(hypervascular)

Vascularised. Callus formation present on x-ray

Elephant foot type - abundant callus

Horse hoof type - less abundant callus

} Adequate biological response, poor mechanical environment for healing.

Oligotrophic - No callus on x-ray. Inadequate biological response.

b) Atrophic or avacular Ischemic or cold on bone scan. Represent loss of biological response to injury.

Avascular nonviable/atrophic nonunion divided into

1) Torsion wedge 2) Communited

3) Defect 4) Atrophic

II) **Paley et al** divided nonunion clinically and radiologically into two major types

Type A (Bone loss < 1 cm)

Al - Non union with a mobile deformity

A2 - Nonunion with a fixed deformity

A2 -1 Stiff non-union without deformity

A2 -2 Stiff non-unions with a fixed deformity

Type B (Bone loss > 1 cm)

B1 - Nonunion with a bony defect

B2 - Nonunion with loss of bone length

B3 - Nonunion with bony defect and loss of bone length

This classification system is further modified by the presence or absence of infection. **- Maurizio Catagni's classification**

Al - Non infected mobile nonunion

A2 - Non infected stiff hypertrophic nonunion without deformity

A3 - Non infected hypertrophic nonunion with deformity

Bl - Non infective nonunion with bone defect of up to 5 cms

B2 - Non infective nonunion with bone defect exceeding 5 cms

B3 - Non infective nonunion exceeding lOcms with local scarring

C1 - Infected nonunion with atrophy

C2 - Infected nonunion with hypertrophy without deformity

C3 - Infected nonunion with hypertrophy and deformity

C4 - Infected nonunion with bone gap of less than 5 cms

C5 - Infected nonunion with bone gap between 5 and 10 cms

C6 - Infected nonunion with bone gap exceeding 10 cms

The University of TEXAS Classification

Based on the location of infection and modified by immune

competence of the host.

Type 1 : Intramedullary

Type 2 : Superficial

Type 3 : Local

Type 4 : Diffuse with segmental bone loss

Type A : Healthy immune system

Type B : Local or systemic compromise of immune system

Type C : Severe compromise of immune system

V - WIELAND'S Classification

Type 1 : Bone exposed and soft tissue infection present

Type 2 : Circumferential cortical and endosteal infection present

Type 3 : Cortical and endosteal infection combined with segmental bone loss

VI - AO - Classification :

1) Infected non draining non-union (Active / Quiescent)

2) Infected Draining non-union

VII - KULKARNIS Classification

Classification of infected non-union is based on the severity of infection, apposition of fragments, presence or absence of deformity.

Type 1 : Mild infection

- Beads of pus on pressing

- Fragments in alignment
- With or without an implant
- No gap
- No deformity
- No shortening

Type 2 : Moderate infection :

- Fragments in apposition
- No gap or gap < 2 cm
- No deformity
- No shortening
- Moderate infection with a large or small wound

Type 3 : Severe Infection

- Pouring pus
- Gap > 2 cms
- With deformity
- Shortening > 2 cms

Pathophysiology

PATHOPHYSIOLOGY OF INFECTED NONUNION

Union has been shown to occur in the presence of active infection. Uncontrolled infection, however causes non-union. The inflammatory response to the infection process leads to an excessive remodelling response causing osteolysis, which further slows the rate of union.

Pathophysiology of infections after internal fixation of fractures:

Infection complicating internal fixation of fractures is a serious complication that is difficult to treat whenever metallic implants are implanted in vivo, successful bio integration requires that host cells colonize the highly reactive implant surface. Bacteria such as staphylococci can also become adherent to metallic or polymeric implants and will compete with host cells for colonization of the implant surface. Once adherent these bacteria form a bio film and undergo phenotypic changes that make them resistant to the normal host immune response as well as to antibiotics. Furthermore, metallic implants themselves cause specific deficits in the function of the local immune system that may render the host response to infection inadequate. Associated soft tissue injury causes greater impairment of local immune function. Despite the potentially detrimental impact of internal fixation, fracture stability is of paramount importance in achieving fracture union and in preventing infection. Because of the potential for infection whenever internal fixation is utilized

appropriate prophylactic antibiotic coverage for staphylococci and gram negative organisms should be provided. Open wounds and severely damaged soft tissues require aggressive management so that a viable soft tissue envelope is maintained around the implant. Host factors such as smoking and malnourishment should be corrected. Early diagnosis and aggressive treatment of implant related infection with antibiotics, debridement and maintenance of stable internal fixation are essential to successful treatment.

Bacterial adherence to biomaterials and tissue. The significance of its role in clinical sepsis.

A study by AG Gristina and JW costerton

The direct examination of tissue and biomaterials from prosthesis related infections of 25 patients showed that the causation bacteria grew in glycocalyx enclosed bio films that were adherent to surface of biomaterials and tissue in 76%. This high rate of recovery of adherent bio film mediated growth suggests that the process occurs commonly in the presence of a foreign body or biomaterial related infection. Because of the adherent mode of growth of the infecting organisms, accurate microbiological sampling was difficult. The analysis of swabs of excised tissue and of prosthetic surfaces often yielded only one species from what was a polymicrobial population based an election microscopic studies.

The process of surface adhesion and biofilm development is a survival

strategy employed by bacteria. This process is designed to anchor microorganisms in a nutritionally advantageous environment. Bacterial attachment to a surface can be divided into several distinct phases, including primary and reversible adhesion, secondary and irreversible adhesion, and biofilm formation

A **glycocalyx is the glue that holds the biofilm fast to the colonized surface and is a complex of exopolysaccharides of bacterial origin (slime layer) and trapped exogenous substances.**

Costerton et al. define a biofilm as "a structured community of bacteria" When fully hydrated, the glycocalyx is predominantly water. In most species, the glycocalyx is predominantly anionic and creates an efficient scavenging system for trapping and concentrating essential minerals and nutrients from the surrounding environment. As an added advantage, the glycocalyx provides a certain degree of protection for its inhabitants against certain environmental threats, including biocides, antibiotics, antibody, surfactants, bacteriophages, and foraging predators such as free-living amoebae and white blood cells. In essence, the glycocalyx creates a three-dimensional force field that surrounds, anchors, and protects surface-bound bacteria.

INVESTIGATIONS

1) X-rays - Standard AP, lateral

In majority of cases, this is all that is required to confirm nonunion. Examination under fluoroscopy, stress views to check for motion can occasionally be helpful.

2) Tomography

Helps to identify persistent fracture line in cases of hypertrophic nonunions in which x-rays are not diagnostic and pain persists at fracture site. Computed tomography and MRI are replacing linear tomography if no hardware is present. Inspite of all these investigations undetected infection is the main diagnostic dilemma in evaluation of nonunions.

3) Radionuclide Scanning

1) Technetium - 99 diphosphonate . Detects repair process in bone (not specific). 2) Gallium - 67 citrate

Accumulate at site of inflammation (not specific). Sequential technetium or gallium scintigraphy. Only 50-60% accuracy in subclinical osteomyelitis. **Esterhai et.al. J Ortho Res. 1985 .Smith MA et.al. JBJS Br 1987.**

Indium III - Labeled Leukocyte Scan

Good with acute osteomyelitis, but less effective in diagnosing chronic or subacute bone infections .Sensitivity 83-86%, specificity 84-86%. Technique is superior to technetium and gallium. **Nepola JV e.t. al JBJS 1993, Merkel KD e.t. al. JBJS 1985**.

4) MRI

Abnormal marrow with increased signal on T2 and low signal on T1 Can identify sequestrum, sinus tracts. Mason: diagnostic sensitivity of 100%, specificity 63%, accuracy 93**%. Berquist TH et.al. Magn Res Img. Modic MT et.al. Rad. Clin Nur Am 1986 Mason MD et.al. Rad. 1989.**

5) Tissue Culture

Protocol: Antibiotic discontinued for 72 hours prior to culture

Multiple representative culture specimens should be obtained. Cultures sent for gram stain, aerobic, anerobic, fungal, and acid fast studies. Open biopsy techniques can be inconclusive due to problem of detecting bacteria protected by an external glycocalyx. **Gristina AG el.Al Inst Con Lect 1990.**

History of infected nonunion Treatment

HISTORY OF INFECTED NONUNION TREATMENT

Good judgement is required to treat a nonunion of an infected fracture. Three different methods of treatment have been recommended for this difficult problem.

1. Conventional or classic method
2. Active or modern method
3. Pulsed electromagnetic fields

Ilizorov method is a recent method of treating infected non-union.

1. Conventional Treatment:

The conventional treatment has been in vogue for many decades. The aim of conventional treatment is to convert an infected and draining non-union into one that has not drained for several months and then to promote healing of the nonunion by bone grafting. This method of treatment often requires one or more years to complete and usually results in stiffness of adjacent joints. Time is given for the skin to heal well before final fixation is done.

Stage I :

Wound is thoroughly saucerised and all foreign and infected or devitalized materials are removed to provide a vascular bed. Any gross overlapping and displacements of the fragments are corrected. Fixation is done either by internally or externally. Antibiotics are used both parenterally

and locally after surgery.

Stage II :

After 4-7 days when a thin layer of granulation tissue has covered the wound, a split thickness skin graft is applied. The split graft is replaced by a full thickness pedicled skin graft 4-6 weeks after the wound has healed from the operation.

Stage III:

When the clinical sign of infection have subsided, the skin over the bone is good and non-union persists, bone grafting must be considered. Controlling infection before attempting bone grafting always has been a sound clinical principle in the conventional treatment of non-union.

2. Active treatment:

The object of active treatment is to obtain bony union early and preserve motion in the adjacent joints. Judet, Patel, Weber and Cech described this method. The first step is restoration of bony continuity. This takes absolute priority over treatment of the infection. The nonunion is exposed through the old scar and tissues. The ends of the fragments are then decorticated subperiosteally forming many small osteoperiosteal grafts, any graft that become detached are discarded. Next all devitalised and infected bone and soft tissues are removed. Then the fragments are aligned and stabilised usually by an external fixator. Compression is applied across the

non union if possible. Weber and Cech then inserted autogenous cancellous bone grafts. Internal fixation with a plate is used only when drainage has already ceased, and then the approach is away from the area of old drainage or when no other method of fixation is possible and the infection is mild. Finally a tube for suction drainage is inserted and as much of the wound as possible is closed, any remaining open area is covered by a biological dressing, systemic antibiotics are given.

Disadvantages :

Both conventional and active methods had their own disadvantages.

1. Required multiple procedures
2. Poor patient compliance
3. Joint stiffness

Electric and Electromagnetic Stimulation :

External electrical stimulation is especially advantageous in infected nonunion management or when surgical intervention is contraindicated. These methods are either invasive, requiring the implantation of electrodes or semi invasive requiring percutaneous application of multiple electrodes. Devices that use inductive coupling differ in their configuration some try to recreate the Helmholtz configuration and others use a U shaped coil. Device was used for more than 3 hours a day. Nonunion healed as readily as those from 9 -12 months. Also infected nonunions were as likely to heal as

noninfected nonunions, and fracture gaps up to 1 cm did not adversely affect the outcome. De Hass et al also found that a high percentage of infected non-union healed with electrical stimulation compared with uninfected nonunions. However they recommended that infected fractures be debrided before electrical stimulation.

Ilizarov Method :

According to Ilizarov, to eliminate infection and obtain union, vascularity must be increased. In his approach this is achieved by corticotomy and the application of his circular external fixator. Catagni reported that, although union was obtained, infection was not always eliminated. For atrophic nonunions with diffuse infection or sequestrated bone open resection of the infected segment is performed and bifocal compression is used.

Disadvantages of Ilizarov method :

1. Poor patient compliance
2. Cumbersome procedure
3. Pin tract infections
4. Muscle contracture and joint stiffness
5. Systemic antibiotic toxicity

Principles in the Management of Infected Nonunion

PRINCIPLES IN THE MANAGEMENT OF INFECTED NONUNION BY ANTIBIOTIC CEMENT IMPRENATED KUNTSCHER NAILS

Principles of management of infection in bones by **Norden et al** in 1994

1. **Complete microbiological diagnosis.**
2. **Assessment of host defence status.**
3. **Definition of extent of local disease.**
4. **Correct antimicrobial therapy.**
5. **Surgical debridement of necrotic tissue.**
6. **Obliteration of dead space.**
7. **Restoration of functional skeletal stability.**
8. **Rehabilitation**.

The principles of treatment are infection control, stabilisation of fracture, soft tissue coverage, and bone grafting of ununited fractures and large bone defects.

Infection control includes debridement, irrigation, culture and appropriate antibiotic therapy. In chronic osteomyelitis obtain aerobic, anaerobic and fungal cultures. Recent studies have advocated taking of multiple deep cultures from purulent material, soft tissue.

Marrie and Costerton postulated that different organisms may be growing in isolated microenvironments. Sampling differences and bacterial viability may influence the culture results.

Stabilization of the ununited fracture or non union is essential. Soft tissue coverage may require the use of local muscle flaps and free vascularised muscle flaps for soft tissues defects. These may also be helpful by bringing about new blood supply.

Surgical Consideration :

Tourniquets :

Tourniquet applied whenever possible except in patients with significant peripheral vascular disease. Exsanguination avoided. The tourniquet improves haemostasis and they facilitate identification of the infection process.

Debridement:

Atraumatic approach with gentle handling of soft tissues with complete removal of devitalized tissue until fresh bleeding occurs. **Treuta et al emphasized the importance of adequate debridement in wound management**. The local anatomy may be altered as the cases are post traumatic or post surgical which should be taken into consideration. Due to soft tissue scarring and fibrosis of nature soft tissue dissection is difficult.

PRINCIPLES OF DEBRIDEMENT

1. **Adequate incision.**
2. **Soft tissue stripping to the minimum.**
3. **Periosteum is stripped only from cortical bone intended for debridement. periosteum over other regions strictly preserved.**
4. **Reactive new bone formation surrounding areas of chronic infection is living and is not debrided.**
5. **Scar and sinus tract excision in toto.**
6. **Tension free wound closing by mobilising the margins.**

Good wound drainage.

Thorough debridement of all sequestra and desiccated bone is essential. Viable infected bone, not removed so as not to create large bony defects. Viable bone bleeds, whereas necrotic bone does not. Osteotome is used to superficially shave the outer cortex of the questionable bone results in small areas of pinpoint sites of bleeding Paprika sign, indicate adequate vascular flow. Evacuate all pus and abscess and remove all necrotic and infected soft tissue. Intramedullary unhealthy granulation tissue debrided by adequate reaming of canal.

Irrigation :

Use copious amounts of irrigating fluid, which cleanses the area of purulent exudates, loose soft tissue and bony fragments and decreases the bacterial

count. With regard to delivery of irrigation, high pressure pulsatile lavage appears to be most effective for removal of bacteria and other contaminants. Sterile saline solution either alone or with an additive is commonly used for irrigation.

The available additives are divided into 3 general categories.

I Antiseptics - Povidone Iodine, Chlorhexidine gluconate Hexa chlorophene

II Antibiotics - Bacitracin

III Soaps

Soaps remove microbes instead of killing them, and have least injurious effect on osteoblasts and osteoclast. The irrigation volume varies. From the available evidence, it is not possible to recommend any particular additive for the irrigation of medullary canal.

We used 9 litres of normal saline for irrigating the infected wounds. After irrigation, the medullary canal is reamed up to its maximum capacity to allow fresh bleeding and for maximum space for the prepared nail to be inserted. To limit the thermal effects of reaming saline soaked gauze pad draped over subcutaneous aspect of tibia and saline irrigation of medullary canal done.

Wound Management:

The decision to leave a wound opens or to close it, requires careful

judgement. Severe infections following abscess formation with cellulitis and swelling the wound should be left open. In some cases of early post operative infection, the wound may be closed with drain as long as the wound debridement is satisfactory.

In some cases bone or metal may be exposed if the wound is left open. A partial closure over the bone or metal may be desirable as long as an adequate pathway has been provided for drainage. When there is any doubt, it is safest to leave the wound open. If the wound is closed, the wound site must be examined daily for any signs of infection, if such signs appear the wound must be opened. Many wounds heal nicely by secondary intention. In case of large wounds or when delayed closure is preferable, do not attempt closure until two criteria are met.

First, the wound should appear clinically healthy with clean granulating tissue and without any purulent exudates or necrotic tissue. If infected necrotic tissue are present redebride the wound until it appears healthy. Second, once clinical appearance of the wound is clear, take quantitative tissue culture and do Gram stains. Wounds with either a positive Gram stain or quantitative tissue cultures with a bacterial count greater than 10^5 organisms should never be closed. Thorough initial debridement followed by an en bloc excision of the wound at closure with or without plastic procedures.

Drains :

Wounds are closed with vario drain 14g to allow for adequate drainage. Penrose drains made of rubber left for long periods can cause foreign body granulomas. we do not use Penrose drains in orthopaedic infection management.

Remove the suction drain in 48-72 hours when collection is less than 30ml/24 hrs. The drain allows the removal of all hematoma and tissue fluid and the collapse of the potential dead space. The drain should be removed under sterile conditions and the tip cut off and sent for culture and sensitivity tests. Positive culture of the drains tip is a bad prognostic sign.

Wound Packing :

The purpose of leaving a wound open is to allow drainage, packing with gauze should not obstruct drainage. If it does, purulent exudates will be retained in the wound, causing tissue breakdown and necrosis with secondary cellulitis or abscess formation. Wick drainage should be perpendicular to the open wound to allow free drainage. Wicks can be either povidone iodine soaked gauze or plain gauze. The size varies with the size of the wound. The ends of the wicks should always protrude through the skin edges to allow easy access and removal and to prevent retention.

Materials and Methods

MATERIALS AND METHODS

This is a prospective study conducted in kilpauk medical college hospital between July 2008 to November 2009 in 25 cases of infected nonunions, chronic osteomyelitis (with bone defects after debridement), implant failure with nonunion and infection following plating as well as nailing. One female and twenty four male patients (age range, 21-65 years) were included in the study. Twelve of the patients were Grade IIIB compound, two were Grade II Compound, two were Gr I compound and nine were closed fractures initially. All twenty five patients had infected nonunion at presentation, and fourteen patients had bone defect ranging from 1 to 2.5cms after initial debridement. Average follow-up was 8 months (range, 4-18 months). At the latest follow-up, except for one patient all others had no clinical signs of infection.

INCLUSION CRITERIA

1. Diaphyseal fractures of femur and tibia with infected nonunion.

2. Operated cases of femur and tibia with implant failure and nonunion following infection.

EXCLUSION CRITERIA

1. Intra articular fractures.

2. Segmental bone defect of more than 3 cm.

MATERIALS USED

1. Kuntscher nail

2. Kuntscher diameter gauge

3. Measuring Scale

4**.** Bone Cement

Bone cements are orthopaedic acrylic radioopaque sterile cements that allow an immediate and stable fixation of surgical implants into the bone. Available as

1. Standard viscosity (digital use) 2. Low viscosity (syringe use)

Bone cements are composed of two components

Powder (polymer)

1. Polymethyl methacrylate - polymer
2. Benzyl peroxide - initiates polymerization
3. Barium sulphate - Radio opaque contrast medium for X ray
4. Gentamycin sulphate 2 %

Liquid (monomer)

1. Methyl methacrylate - monomer
2. Butyl methacrylate - co monomer
3. N, N dimethyl p-toluidine - promotes cold curing of the finished therapeutic compound
4. Hydroquinone - prevents premature polymerization.

Sterilized by beta radiation

INSTRUMENTS AND MATERIALS USED

Preparation of the Bone cement

To mix, empty the contents of the packet containing the powder into a sterile inert mixing device. The liquid from the ampoule is added to the powder. Stirring is done until a dough like mass is formed. The dough like mass is ready for manipulation. The mixing and manipulation process should be at least 4 minutes. The completion of polymerisation occurs with an exothermic reaction with considerable liberation of heat.

Hardening time:

From the start of mixing, the final hardening occurs in standard viscosity bone cement 7.5 - 8.5 min. Low viscosity bone cement 9.5 - 10.5 min at ambient temperature of 23 C.

Adverse reactions:

1. Cardiac arrest
2. Myocardial infarction
3. Pulmonary embolism
4. Cerebrovascular accident

Most frequent reactions

1. Transitory fall in blood pressure
2. Thrombophlebitis
3. Haemorrhage
4. Loosening and displacement of prosthesis
5. Surgical wound infection

6. Trochanteric bursitis

7. Trochanteric separation

Storage:

Store in dark below 25° C. Liquid component flammable.

Pack presentation:

- Sterile packet contains 20 gm or 40 gms of sterile powder polymer.

Sterile ampoule containing 10 ml or 20 ml of sterile liquid monomer.

5. Antibiotics in Bone Cement:

The infection rate in early series was up to 15% or more. The initial contamination, soft tissue injury, immunity status of the patient, and theatre sterility all affect the outcome of surgery. The infection rate is now down to 1-2%. Perioperative systemic antibiotics have helped to reduce postoperative sepsis.

In 1969, Buchholz and Engelbrecht first proposed a totally different approach incorporating antibiotic powder directly into the bone cement. This work is supported by the data from invitro pharmacokinetic studies of Wahlig and Dingeldein (1980).

Mechanical testing of the antibiotic impregnated bone cement confirmed that the antibiotic when incorporated in the amounts usually used for clinical purposes had no significant influence on the strength of the bone cement both in compression and tension.

Antibiotic Agents:

Antibiotic agents that are heat stable, available in powder from and active against suspected pathogen are appropriate choices for local therapy. Amino glycosides and vancomycin satisfy these criteria.

Fluroquinolones, tetracycline and polymyxin B, are broken down during the exothermic process of cement hardening, hence cannot be used with bone cement.

Ideal Antibiotic in Bone Cement

1. Should be available in powder form.
2. Broad spectrum-effective against gram positive cocci and MRSA.
3. Thermo stable.
4. Less toxic.
5. Resistance uncommon.
6. Cost effective.
7. Non allergic.

Antibiotics commonly used in bone cement

Vancomycin, Teicoplanin, **Gentamycin,** Erythromycin, Tobramycin, Colistin, Cefazolin, Cefotaxime, Clindamycin, Amphotericin B and Ticarcillin.

Gentamycin

Broad spectrum of action. Active against Escherichia coli, klebsiella,

enterobacter, serratia, proteus, acinetobacter, pseudomonas, staphylococcus, salmonella and shigella. Binds to ribosomes and inhibits bacterial protein synthesis. Bactericidal action is concentration dependent. Side-effects are ototoxicity, nephrotoxicity and accentuates neuromuscular blockade. Long term efficacy with studies showes persistency of antibiotic within bone upto 24 months.

Vancomycin:

It is a tricyclic glycopeptide antibiotic derived from Amycolatopsis orientalis. It assumed special significance due to its efficacy against MRSA, strep viridans, enterococcus and clostridium difficile. It is bactericidal to gram positive cocci, neisseria, clostridia and diphtheroids. It acts by inhibiting bacterial cell wall synthesis by preventing their cross linking. It is not absorbed orally. After intravenous administration it is widely distributed, penetrates serous cavities, inflamed meninges and is excreted by glomerular filtration, with a t1/2 of 6 hours. Excreted unchanged in kidney. The incidence of nosocomial infections in hospitalized patients varies between 5% and 15%. It is the drug of choice for the treatment of infections due to methicillin-resistant staphylococci, corynebacterium jeikeium, and resistant strains of streptococcus pneumoniae. Vancomycin is an alternative drug for serious staphylococcal and streptococcal infections, when allergy precludes the use of penicillins and cephalosporins

Toxicity:

1. Plasma concentration dependent nerve deafness.
2. Dose related nephrotoxicity.
3. Skin allergy, thrombophlebitis and anaphylaxis
4. Hypotension following intravenous injection due to histamine release IgE mediated mast cells and basophil degranulation ending in histamine release.
5. Rapid intravenous injection has caused chills, fever, urticaria and intense flushing called Redman syndrome**.**

Available as 500 mg/1000mg vial. Dosage 500mg 6 hourly or 1000mg 12 hourly infused intravenously over one hour.

- **Vancomycin has much slower and more consistent elution characteristics. Elution studies show biphasic leeching of antibiotics with early peak concentration and late plateau phase.**
- **Gentamycin elution from bone cement is increased by vancomycin.[15]**
- **Vancomycin and gentamycin have no adverse effects on osteoblasts and callus formation.**
- **Vancomycin upto 4 gms and gentamycin upto 2% per 40gms do not alter the mechanical property of bone cement.**

At 2 years follow up there were no renal, vestibular or hearing changes. Vancomycin has much slower and more consistent elution characteristics than tobramycin as much as 4 gm of Vancomycin (as well as 4.6 gm of tobramycin) can be used per batch of cement.

Evans et al, used 4 g of vancomycin and 4.6 g of tobramycin per 40 gm batch of cement in 54 periprosthetic joint infections at 2 year follow up there were no renal, vestibular, or hearing change.

Masri et al, authors conclude that at least 3.6 g of tobramycin and 1 g of vancomycin per package of bone-cement for antibiotic-loaded cement spacers are used in 2-stage exchange arthroplasty for infected total hip and knee arthroplasties; there was a statistically significant increase in elution of vancomycin when dose of tobramycin was increased from at most 2.4 g to at least 3.6 gm.[14]

Springer et al total antiobiotic load of 10.5 g of vancomycin and 12.5 g of gentamycin was clinically safe, with no evidence of acute renal insufficiency or other systemic side effects. **Journal of Bone and Joint Surgery (B), Vol 91-B, Issue SUPP-II, 305.**

Elution of antibiotics follows a biphasic pattern, with an initial rapid phase and a secondary slow phase. Elution is at its maximum during the first day, greatly declines on the second day, and then gradually decreases over time and stabilize between days 5 and 10.

Animal and clinical studies consistently have shown high local concentrations and undetectable or very low serum levels of the locally delivered antibiotics with no systemic toxicity. The systemic absorption of the locally delivered antimicrobial agent is limited and results in extremely low serum levels, which have ranged from 0.3 to 0.5 µg/mL in the case of gentamycin, recorded by **Wahlig et al.** [38]

In animal experimental models, no apparent effect on fracture healing was noted with the use of gentamycin, or vancomycin at levels achieved with systemic therapy.

We used 3 gms of vancomycin to 40 gms of gentamycin simplex bone cement. Coating on nail allows for increased surface area which results in better antibiotic elution.

Microorganism in infected non-union:

Currently most infections are caused by gram positive cocci and gram negative bacilli. However methicillin resistant staphylococcus aureus (MRSA) has recently emerged as a potential cause of infection.

Surgical Technique

The surgical technique involves a series of steps, each of which is critical for successful results.

Pre-Operative Evaluation

1. Complete blood count

2. ESR: Measurement of increased rate of setting of erythrocytes is an important lab test in evaluation of disease activity in patients with infections. Peak elevation occurs at 3 to 5 days after infection and returns to normal approximately 3 weeks after treatment is begun. Done by Westergren method.

Normal valves are 0-9 mm per hour for men, 0-20 mm / hr for women. In routine orthopaedic procedures, maximum of 25 to 40 mm / hr is reached in 4 days which gradually decreased to normal over 1-2 weeks.

3. C - Reactive protein

An acute phase protein that can be used to follow the course of acute infections. Increases within 6 hours reaches peak elevation 2 days after infection, and returns to normal in 1 week after adequate treatment. 10 mg per litre is used as the threshold for THR infection, using this threshold the sensitivity and specificity are both 90%.

4) Culture and Sensitivity

5) Standard Radiographs

The preoperative measurements of the length and diameter of the Kuntscher nail are calculated by using these radiographs. For the femur, the distance from the pyriformis fossa to 1 cm proximal to the top of the intercondylar notch is used as the length of the nail. For the tibia, the length

of the nail is from the proximal tibial articular surface to 1 cm proximal to the ankle plafond.

Debridement

The second step involves thorough debridement of the infected bone and soft tissues and then copious lavage. All the nonviable and infected tissues, including the skin, soft tissues, and bone, undergo debridement until bleeding viable tissue is present at the resection margins. Specimens are obtained of the bone, soft tissues, and any purulent material present and are sent for aerobic and anaerobic cultures and sensitivity.

Preparation of intramedullary canal is a important step. Adequate reaming is done to accommodate a larger diameter nail which ensures more stability.

Fibular osteotomy of middle third fibula done when it is united and distracting the fracture. Fibular osteotomy, unique in treatment of tibial nonunions. Often used as adjunctive procedure to assist with deformity correction and surgical stabilization of tibia. Fibula can distract or unweight physiologic forces seen in the tibia **Teitz, C.C. e.t.al.JBJS 1980.** Concentrates physiologic forces (dynamizes) in tibia to augment mechanical healing environment.

Thorough saline lavage of the medullary canal and the wound is done. The surgical team change their gowns and gloves. The limb is prepared again and redraped before antibiotic cement impregnated nail is prepared.

Antibiotic Cement Impregnated Kuntscher Nail Preparation:

The third step is the preparation of the antibiotic cement impregnated nail under sterile conditions in the operating room. The nail prepared on a separate sterile table. Nail length is measured with guide wire peroperatively. In case of the tibia, after selecting the Kuntscher nail of appropriate length the Herzogs bend of 8 degrees is created with benchpress 5cm from the proximal end of nail. Nail diameter is determined by the peroperative reaming diameter. The medullary canal is reamed upto the maximum diameter possible. kuntscher nail of 8mm or 9mm diameter is chosen and cement coated upto 2mm less than the diameter of the last reamer.

Standard viscosity gentamycin bone cement were used. 40 gm cement was thoroughly mixed with 3 gms of vancomycin following which the polymer was added. When the cement reaches doughy consistency Kuntscher nail is coated and manually rolled upto to uniform diameter. Proximal eye of nail left open while distal nail tip cement is moulded to smooth bullet-nose shape. Nail inspected for spotty coverage and smoothened. The diameter required is checked with Kuntscher diameter

measuring gauge and excess cement is shaved off and nail rerolled before the cement sets and diameter is rechecked. Bone cement is allowed to set for 15 minutes before insertion for the monomer to evaporate and to prevent cement nail debonding.

Bone loss due to primary bone defect following fracture, following sequestrectomy or freshening of bone ends upto 3cms fracture ends are opposed primarily. Bone ends aligned and nail is placed antegradely in tibia and retrogradely in femur.

Nail-cement debonding during insertion avoided by adequate reaming of canal, preparation of appropriate diameter nail and allowing adequate time for cement setting and bonding with nail.

Exchange Nailing

Exchange nailing, if necessary, is done without an antibiotic coating (generally to a larger nail for additional stability) if the infected nonunion has been converted to a nonunion without infection. If there is no infection and union has occurred, the antibiotic-coated IM nail can be left in situ permanently. If both infection and nonunion persist, the IM nail is exchanged for another antibiotic cement-coated IM nail, after a fresh pus culture and sensitivity generally 6 to 8 weeks after the index surgery.

Wound wash given and wound closed in layers with suction drain. Above knee plaster given in tibia, derotation boot in case of femur. Primary

wound closure is done. The antibiotic is leached from the antibiotic coated nails into the postoperative wound hematoma and secretion, which acts as a transport medium.

Post Operative Protocol :

All patients were made to stand with support after 48 hours and toe touching was permitted as per the stability of the fixation diagnosed radiographically. Partial weight bearing with support was started within 2 weeks of fixation. Wound inspected at intervals of 48-72 hours and repeat debridement was done whenever required.

Clinical and radiological features used to assess the progress of bony union at 6 weeks interval till union was sound**. As soon as the wound healed, a patellar tendon-bearing cast was applied in case of tibia and gradual full weight bearing was permitted.** The cast continued till union and was changed every 6 weeks with clinico-radiological assessment. Active physiotherapy for regaining ankle and knee mobility were instituted till the range of movement was satisfactory. A complete blood count (CBC), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP) levels were performed and then at regular biweekly intervals to record rising or falling trends. Cefotaxime is administered during the first 24 to 48 hours after surgery until the results of culture and sensitivity from the samples sent

at the time of surgery are available. The systemic antibiotics are then changed, if necessary, based on these results. Further treatment with oral antibiotics from 6 weeks to 6 months depending on individual patient characteristics and the organism involved.

The patients were followed until there were no evidence of further infection. In patients with knee stiffness knee mobilisation exercises was encouraged and in patients with limb shortening heel and sole rise was given.

Bone grafting :

Bone grafting not done routinely along with the primary procedure. **Bone marrow injection in one patient as staged procedure after 6 months when clinical and blood parameters showed no signs of active infection.** Bone marrow injection preferred over open bone grafting.

Case Illustrations

CASE ILLUSTRATIONS

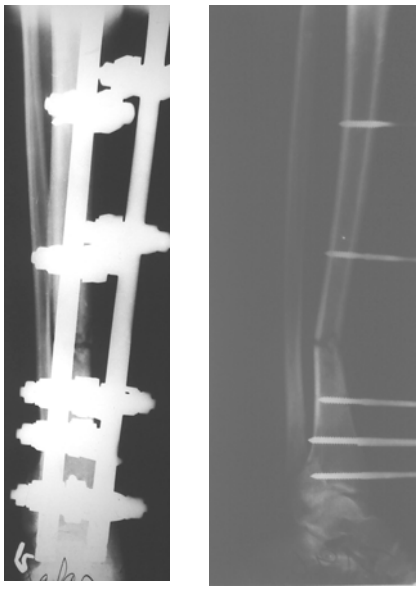
CASE I

Name	:	Dayalan
Age	:	25 years
Sex	:	Male
Occupation	:	Construction worker
Mode of injury	:	Road traffic accident
Initial injury	:	Compound Grade III B fracture both bones right leg
Initial treatment	:	Wound debridement and external fixation
Antibiotic nail	:	5 months after injury
Subsequent procedures	:	Gastrosoleus flap cover
Maurizio-Catagni's classification	:	Type-C4
Paley's Bony Criteria	:	Excellent
Paley's Functional Criteria	:	Excellent

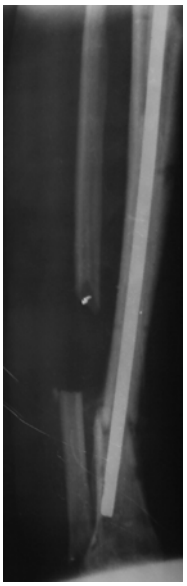
CASE I

AFTER INJURY

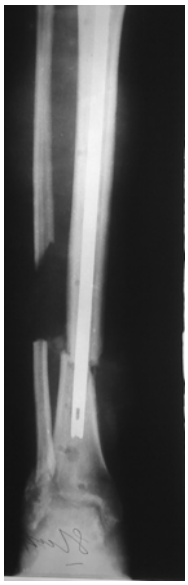
PREOP



IMMED. POST-OP



6 WEEKS POST-OP

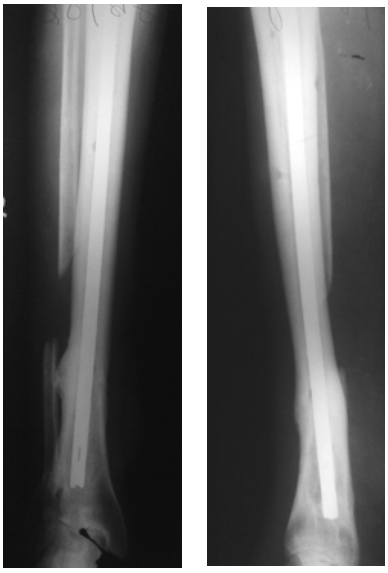


12 WEEKS POST-OP

24 WEEKS POST-OP

12 MONTHS POST-OP

18 MONTHS POST-OP



RANGE OF MOVEMENTS

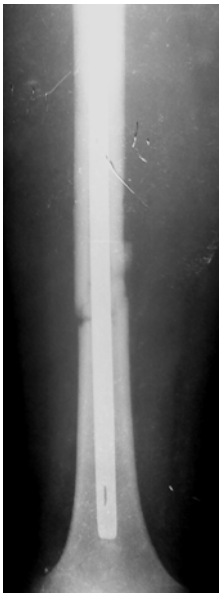
CASE II

Name	:	Murali Mohan
Age	:	21 Years
Sex	:	Male
Occupation	:	Student
Mode of injury	:	Road traffic accident
Initial injury	:	Compound Grade III B fracture shaft of femur right side
Initial treatment	:	Debridement and Above Knee Cast
Antibiotic nail	:	6 Months after injury
Subsequent procedures	:	Nil
Maurizio Catagni's classification	:	Type C4
Paley's Bony Criteria	:	Excellent
Paley's Functional Criteria	:	Excellent

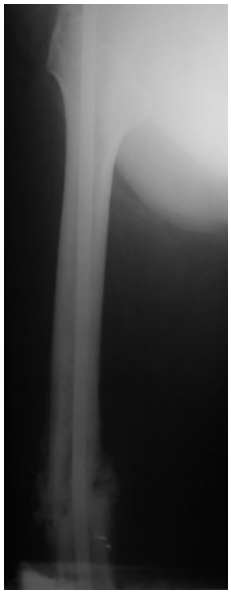
CASE II

PRE-OP

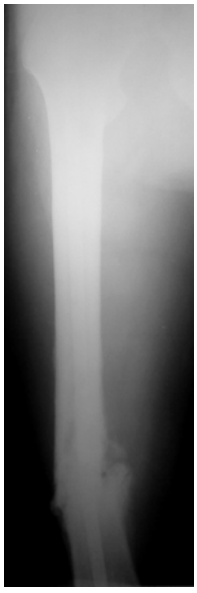
IMMED. POST-OP



6 WEEKS POST-OP



12 WEEKS POST-OP



16 WEEKS POST-OP

6 MONTHS POST-OP

12 MONTHS POST-OP

15 MONTHS POST-OP

RANGE OF MOVEMENTS

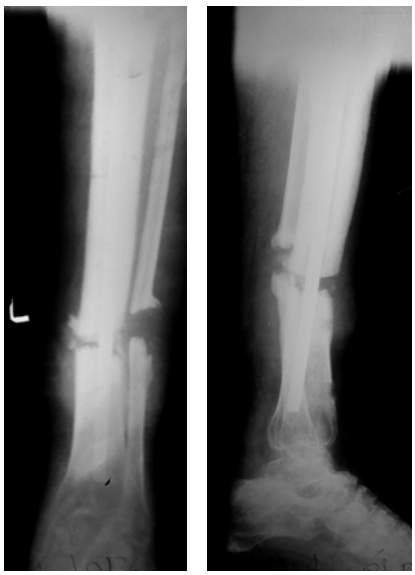
CASE III

Name	:	Natraj
Age	:	35 Years
Sex	:	Male
Occupation	:	Electrician
Mode of injury	:	Road traffic accident
Initial injury	:	Compound Grade III B fracture both bones left leg
Initial treatment	:	Debridement and External Fixation
Antibiotic nail	:	6 months after injury
Subsequent procedures	:	Gastrosoleus flap cover and Bone Marrow injection
Maurizio Catagni's Classification	:	Type-C1
Paley's Bony Criteria	:	Excellent
Paley's Functional Criteria	:	Excellent

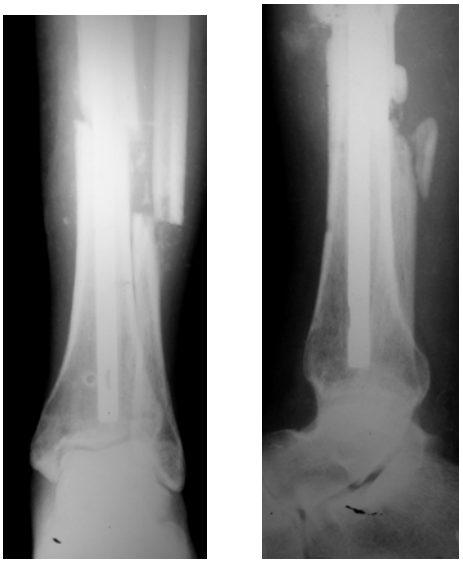
CASE III

PRE-OP

IMMEDI. POST-OP



4 WEEKS POST-OP



16 WEEK POST-OP

6 MONTHS POST-OP

14 MONTHS POST-OP

RANGE OF MOVEMENTS

CASE IV

Name	:	Nagaraj
Age	:	25 Years
Sex	:	Male
Occupation	:	Auto driver
Mode of injury	:	Road traffic accident
Initial injury	:	Closed fracture shaft of femur right side
Associated injuries	:	Crush injury right leg
Initial treatment	:	Below knee amputation right and Plating right femur
Antibiotic nail	:	15 months after plating
Maurizio Catagni's Classification	:	Type-C4
Paley's Bony Criteria	:	Good
Paley's Functional Criteria	:	Good

CASE IV

PRE-OP

IMMEDI. POST-OP

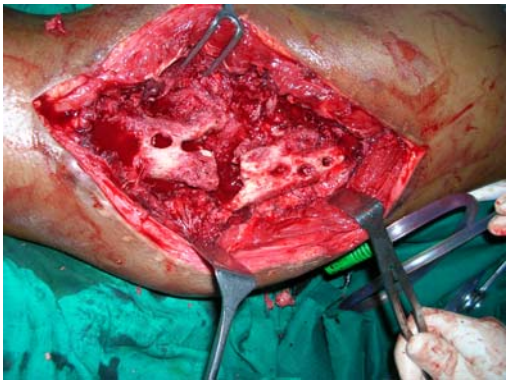
6 WEEKS POST-OP

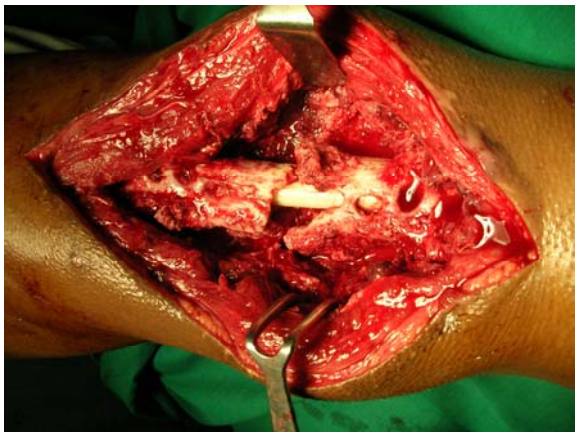
6 MONTHS POST-OP

12 MONTHS POST-OP **15 MONTHS POST-OP**

PRE-OP **POST-OP**

PER-OP PICTURES





RANGE OF MOVEMENTS

CASE V

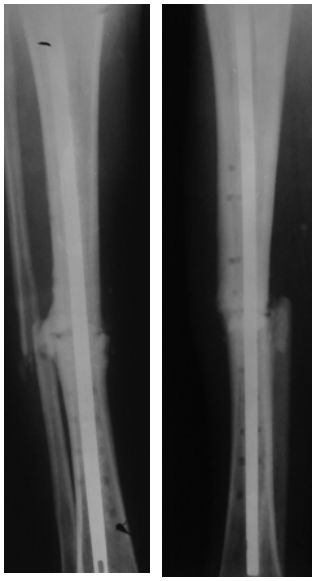
Name	:	Rajesekaran
Age	:	38 years
Sex	:	Male
Occupation	:	Plumber
Mode of injury	:	Road traffic accident
Initial injury	:	Closed fracture both bones middle third right leg
Initial treatment	:	Plating with Bone grafting
Antibiotic nail	:	24 months after initial surgery
Subsequent procedures	:	Nil
Maurizio Catagni' Classification	:	Type C1
Paley's Bony Criteria	:	Good
Paley's Functional Criteria	:	Excellent

PRE-OP

IMMEDI. POST-OP

6 WEEKS

4 MONTHS



12 MONTHS

RANGE OF MOVEMENTS

CASE VI

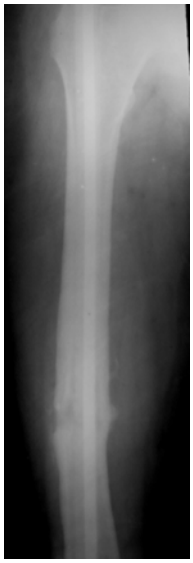
Name	:	Raghu
AGE	:	24 Years
Sex	:	Male
Occupation	:	Hotel worker
Mode of injury	:	Road traffic accident
Initial injury	:	Closed fracture shaft of femur right side
Associated injuries	:	Crush injury right foot and compound Grade III B fracture both bones right leg with 8 cm Segmental bone loss of tibia.
Initial treatment	:	Wound debridement , Illizarov fixator application for lenghthening of tibia and femur open nailing.
Antibiotic nail	:	9 months after initial surgery
Subsequent procedures	:	Nil
Maurizio Catagni's Classification	:	Type C1
Paley's Bony Criteria	:	Excellent
Paley's Functional Criteria	:	Good

CASE VI

PRE-OP

IMMEDI. POST-OP

6 MONTHS POST-OP



12 MONTHS POST-OP

PRE-OP CLINICAL PICTURE

POST-OP CLINICAL PICTURE

Observations

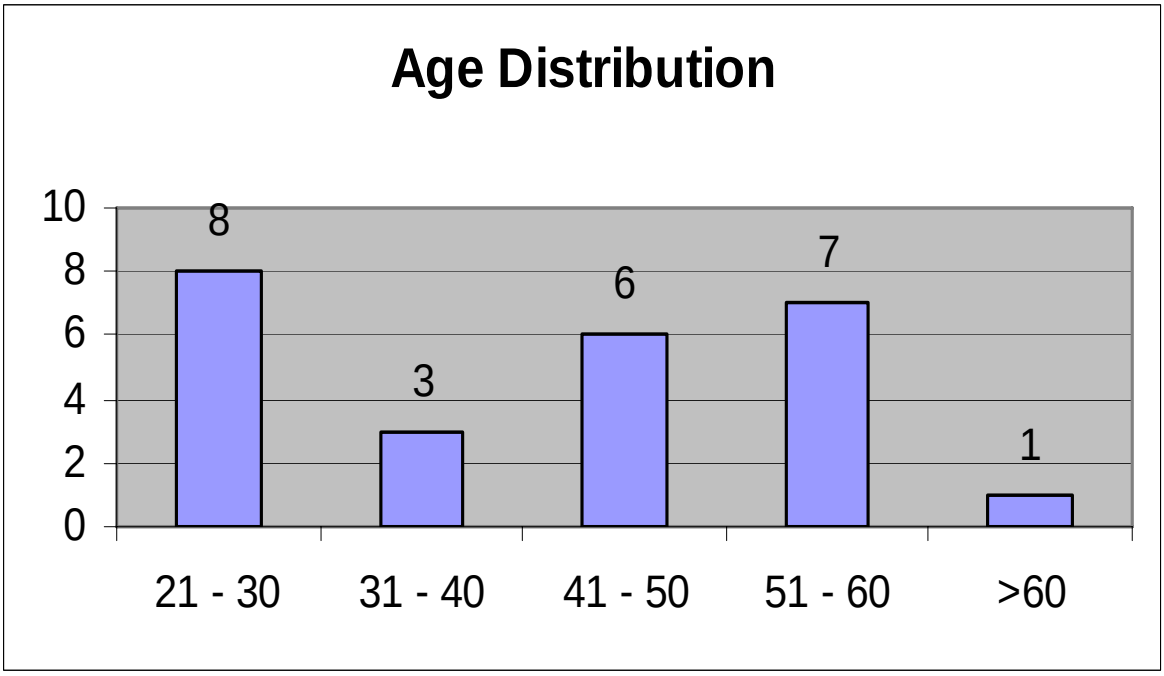
OBSERVATION

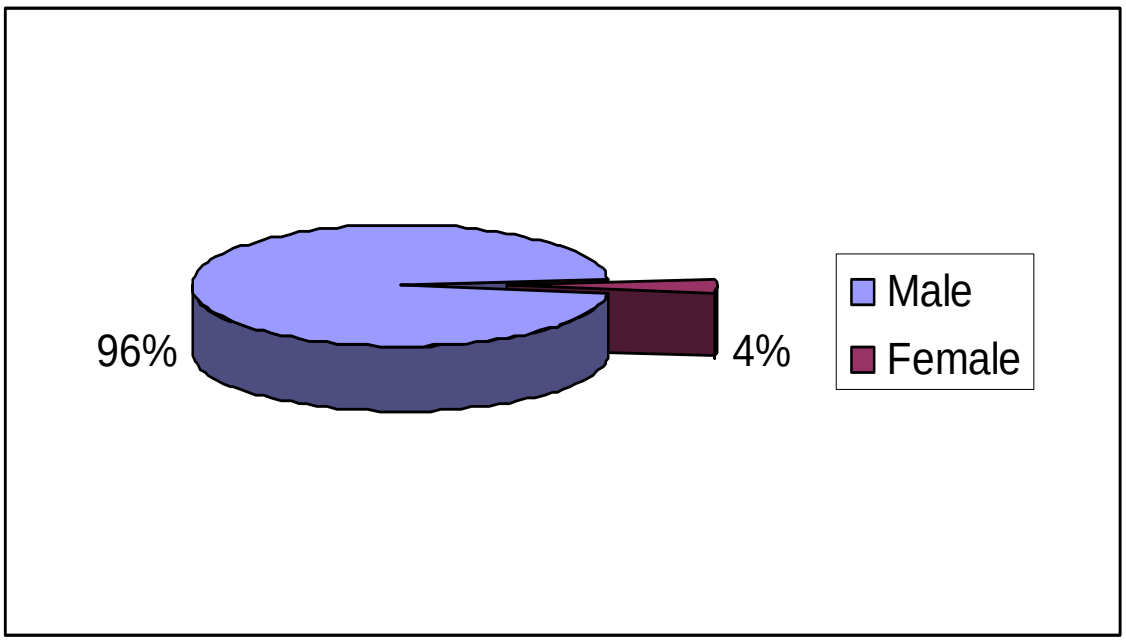
- Of the 25 infected nonunion cases, 16 cases were following compound injuries and 9 were closed fractures initially.
- Higher incidence was noticed in 20-60 years age group.
- Road traffic accidents accounted for all the cases.
- Overall male preponderance was noticed.
- Ten cases required subsequent procedures to achieve bony union.

Study Cases classified by

MAURIZIO CATAGNI'S CLASSIFICATION

C1 – Infected nonunion with atrophy	8
C2 - Infected nonunion with hypertrophy without deformity	5
C3 - Infected nonunion with hypertrophy and deformity	2
C4 - Infected nonunion with bone gap of less than 5 cms	10
C5 - Infected nonunion with bone gap between 5 and 10 cms	0
C6 - Infected nonunion with bone gap exceeding 10 cms	0


Age Distribution
10
8
6
4
2
0
8
3
6
7
1
21 - 30
31 - 40
41 - 50
51 - 60
>60


Sex Distribution
96%
4%
Male
Female

Outcome

OUTCOME

ASSESSMENT CRITERIA:

Bony Union

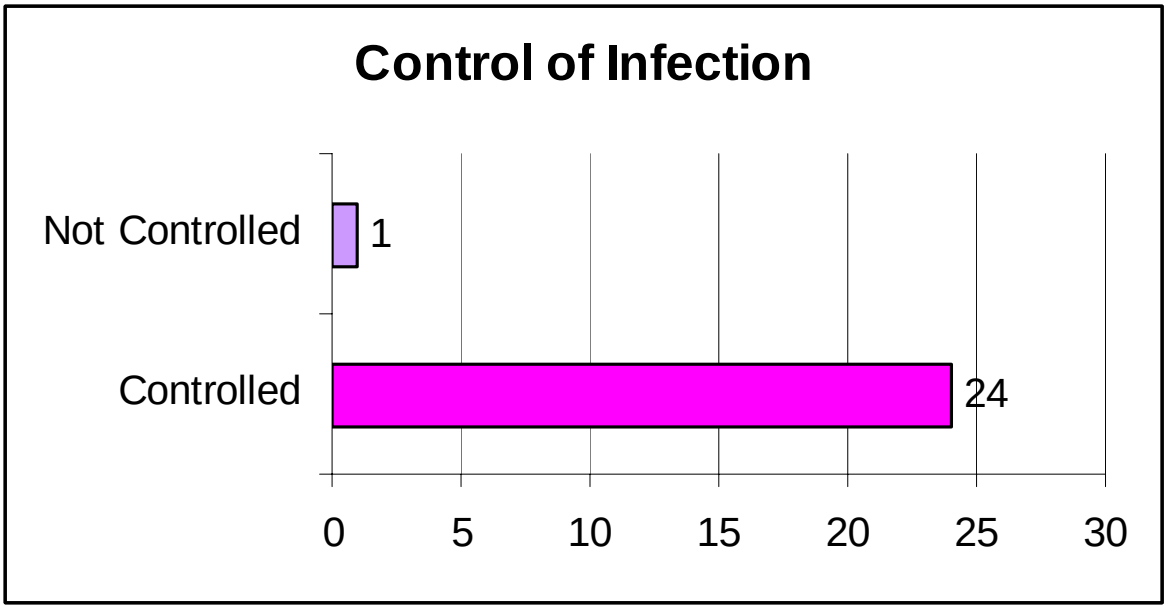
The clinical assessment of the union was mainly based on **complete absence of pain and tenderness at the fracture site**. Radiological criteria for union is **evidence of bridging periosteal and endosteal callus formation as three cortical contact. Bony union recorded in twenty three cases.**

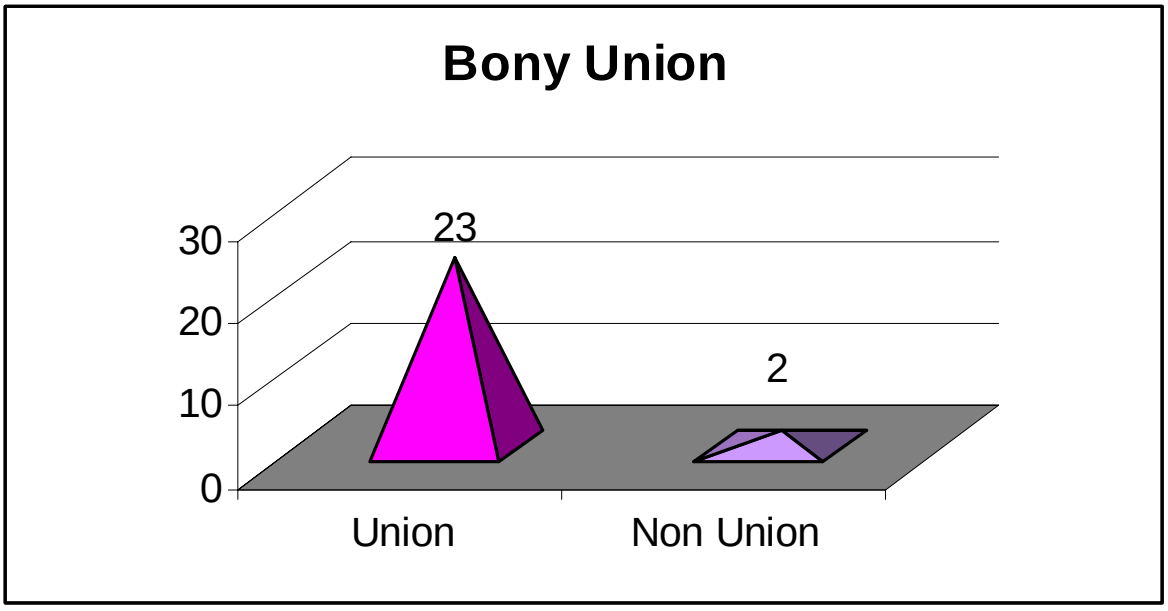
Infection Control

Judged on the basis **of discharge from the wound, clinical signs of inflammation, and laboratory parameters like CBC, ESR, and CRP.** Remission was defined as substantial clinical improvement of symptoms and signs, progressive decline in the sedimentation rate and C-reactive protein, and no further radiographic signs of active infection. Microbiologic failure was defined as the continued isolation of the same infecting organism at the site of infection**. Infection control observed in twenty four cases**.

PALEY' S CRITERIA:

The final results were evaluated by Paley criteria of bony results and functional results.[28, 41.]


Control of Infection
Not Controlled
1
Controlled
24
0
5
10
15
20
25
30


Bony Union
30
20
10
0
23
2
Union
Non Union

PALEY'S BONY CRITERIA

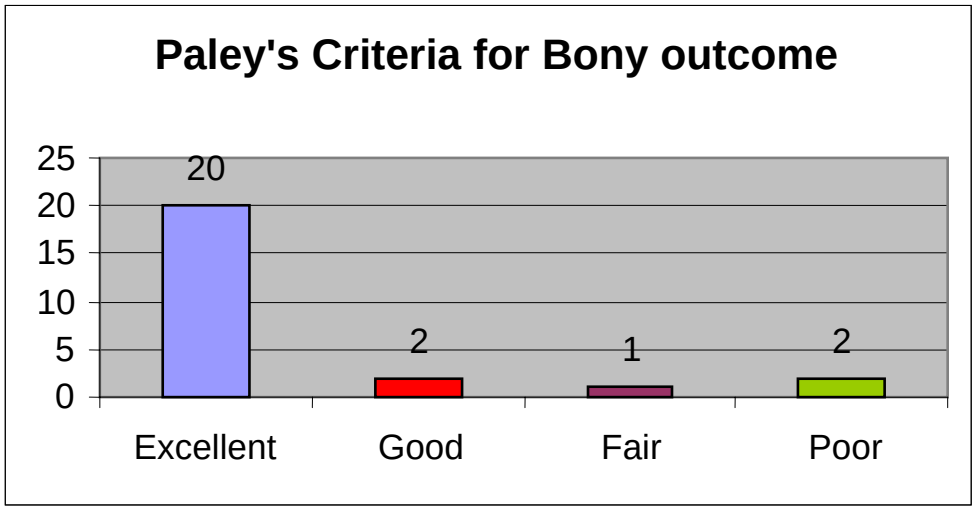
Bony Criteria	Union	Infection	Deformity	Limb length discrepancy
Excellent	✓	Nil	$<7^{o}$	<2.5 cm
Good	✓	With any two criteria		
Fair	✓	With any one criteria		
Poor	Non Union	With or without the above criteria		

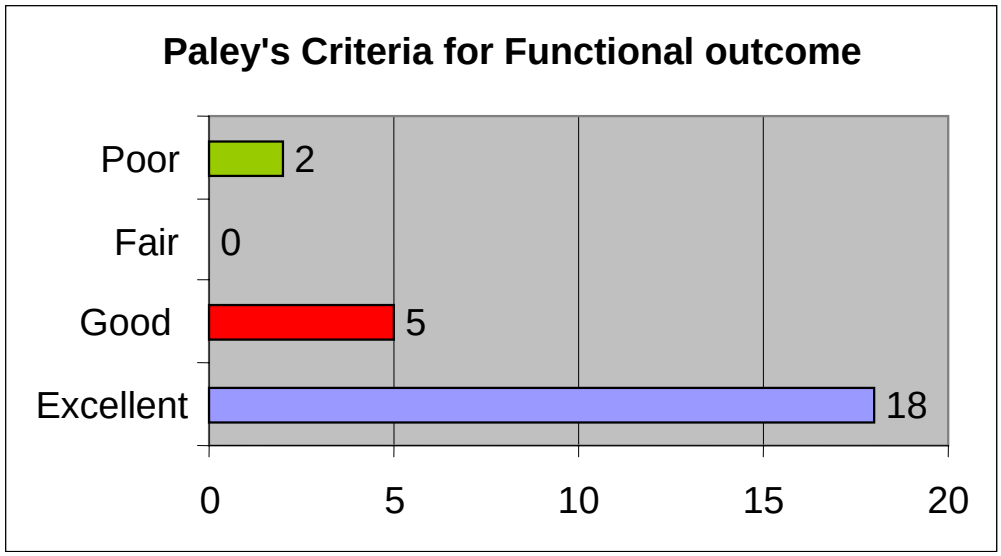
According to these criteria, their were **twenty excellent results, two good results, one fair and two poor results** respectively.

PALEY'S FUNCTIONAL CRITERIA

Functional Criteria	Activity	Significant limp	Equinus Rigidity of Ankle	Soft Tissue Rigidity	Pain
Excellent	Active	-	-	-	-
Good	Active	With one or two criteria			
Fair	Active	With three or four criteria			
Poor	Inactive	Whether any other criteria is present or not			

According to these criteria **eighteen excellent results, five good results and two poor results** respectively were obtained.


Paley's Criteria for Bony outcome
25
20
15
10
5
0
20
2
1
2
Excellent
Good
Fair
Poor


Paley's Criteria for Functional outcome
Poor
Fair
Good
Excellent
2
0
5
18
0
5
10
15
20

1. FOLLOW UP PERIOD

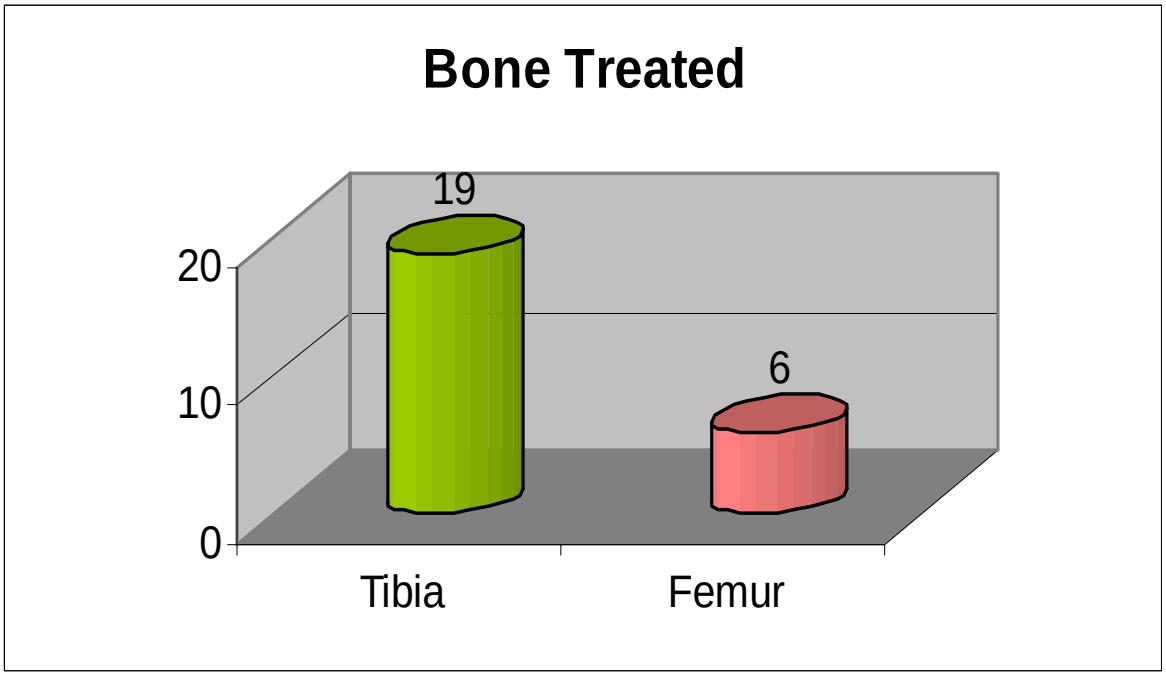
Maximum	18 months
Minimum	4 months
Average	8 months

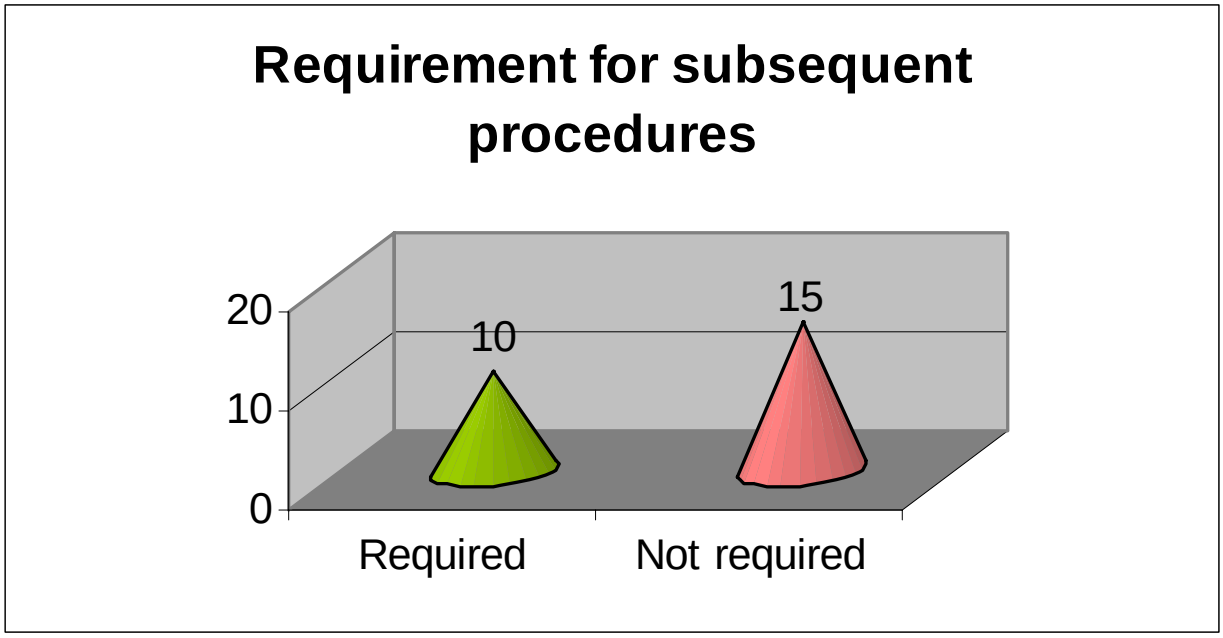
2. CONTROL OF INFECTION

Bone treated	**No. of Cases**	**Infection Controlled**
Tibia	19	18
Femur	6	6

3. BONY UNION

Bone treated	**No. of Cases**	**Union**
Tibia	19	18
Femur	6	5


Bone Treated
19
6
20
10
0
Tibia
Femur


Requirement for subsequent procedures
10
15
20
10
0
Required
Not required

4. RATE OF UNION

Bone treated	Minimum duration	Maximum duration	Mean
Tibia	20weeks	32 weeks	26 weeks
Femur	18 weeks	28 weeks	24 weeks

Two patient with nonunion did not want to undergo additional procedures to achieve bony union. Three patients required exchange nailing, seven patients needed soft tissue procedures to achieve the goals of control of infection and bony union.

Complications

Case of segmental fracture tibia treated with interlocking nail with infection and nonunion, antibiotic nailing done. Lower tibial fracture and fibula united but nail breakage occurred. Managed with fibular osteotomy and exchange nailing.

Antibiotic Kunstscher nailing of femur with distal migration of nail 15 months postoperatively after fracture nonunion. Implant exit done.

One case of nail bending in tibia was noted which was addressed earlier by patellar tendon bearing cast until union. Nail-cement debonding was observed in two cases of exchange nailing, and the free proximal cement mantle was removed.

COMPLICATIONS

NAIL BREAKAGE

PRE-OP

4 MONTHS POST-OP

NAIL MIGRATION

Proximal patellar tendon impingement following weight bearing noticed in one cases of tibia. Implant exit done following union.

Nonunion persisting	2
Infection not controlled	1
Nail bending	1
Nail breakage	1
Proximal nail impingement	2
Distal nail migration	1
Nail cement debonding	2

Discussion

DISCUSSION

Infected nonunions and segmental bone defects demand treatment methods that **offer control of infection and provide stability to the bone to promote union.**[22]

Osteomyelitis is commonly polymicrobial in 70% of patients. The most common infecting organism in the literature and in our study is Staphylococcus aureus.[19,20] **Gentamycin and vancomycin are common choices for local delivery of antibiotics because of their broad spectrum of activity, heat stability, and low allergenicity.** Clinical and experimental studies show them to have **good elution properties from bone cement, and no deleterious effects on bone healing.**[13,15,22]

Control of infection in 24 out of 25 cases in our study is comparable to results of infection control in all cases by **Ashok et al** Indian journal of orthopedics 2009 oct:43(issue 4): 396-402.[4]

All cases were further managed with exchange nailing by Ashok et al, but exchange nailing was done for only 3 cases to achieve bony union in 23 out 25 cases in our study**. Zhang Qiang et** al have shown bony union in only 11 out of 19 cases.[23] **Thonse et al** have shown bony union in 17 out of 20 cases.[22]

Paley et al[41] have shown that control of infection was about 85% and bony union achieved in about 90% cases by illizarov methodology, with our study showing better results in this group of patients.

Rate of bony union average of 26 weeks for tibia and 24 weeks for femur is comparable with results shown by **Han SK et al** of 26.4 weeks for tibia and 31.5 weeks for femur.[8]

Use of external fixators is associated with poor compliance, pin site complications, difficulty due to obesity, which increases the risk of pin site infections. These patients benefit from the antibiotic cement impregnated nailing.[41]

Advantages of antibiotic cement impregnated kuntscher nailing:

1. **High local concentrations of antibiotic - 200 times greater than systemic drug delivery. (Campbell's text book of orthopedics 10th edition).**
2. **Systemic toxicity of antibiotics not observed.**
3. **Antibiotics level above the minimal inhibitory concentration of sensitive organisms.**
4. **Versatility of modifying antibiotic as per the culture report.**
5. **Painful inflammatory response subsides rapidly.**
6. **Daily dressing not required, as wound is closed.**
7. **Post operative morbidity is less, with early rehabilitation.**

8. **Long stay in hospital avoided hence less chances of hospital acquired infections.**
9. **Control of infection and stability in single stage procedure.**
10. **Cost effective.**
11. **Early mobilization causes better patient compliance and comfort.**
12. **Requirement of cumbersome external fixators for prolonged periods not necessary.**
13. **Planning for soft tissue plastic procedures easier.**
14. **Wider surface area of elution allows for high antibiotic concentration along entire length of the bone treated.**
15. **Antibiotic concentration at source of infection not dependent on the pharmacokinetics of the antibiotic.**
16. **Good local concentration of antibiotic even in the presence of extensive scarring and compromised vascularity are the advantages over intravenous antibiotic therapy.**
17. **Patients with elevated renal parameters treated with effective concentration of antibiotic without side effects.**
18. **Overall patient compliance was good and acceptance better when compared to external fixators in our study.**

Conclusion

CONCLUSION

- **Antibiotic cement impregnated nailing provides effective infection control and good stability to promote union, traditionally provided by two separate procedures.**
- **It is advantageous over external fixators, as it eliminates the complications of external fixators and has good patient compliance.**
- **Safe, patient friendly, versatile procedure that could be adapted in hospitals easily.**
- **The method utilises existing easily available instrumentation and materials to manage a complex problem in a highly cost effective way.**

"Antibiotic cement impregnated nailing is a simple, economical and very effective procedure than the traditional methods in management of infected nonunion of femur and tibia".

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Proforma

ANTIBIOTIC CEMENT IMPREGNATED NAILING IN THE MANAGEMENT OF INFECTED NONUNION OF FEMUR AND TIBIA

PROFORMA

Name	IP no.
Age	
Sex	Date of admission
Occupation	Date of surgery
Address/phone no.	Date of discharge

Date of injury:

Mode of injury:

Associated injuries:

Classification:

Bone involved: femur / tibia

Side involved: right / left

Associated systemic / local complications:

Clinical diagnosis:

Pre op evaluation:

- E S R
- C R P
- Pus c/s
- Clinical findings: abnormal mobilitity/sinus with discharge/bone defect
- X Ray findings
- Previous surgery

PER OPERATIVE:

- Nail size:
- Canal c/s:

POST OPERATIVE FOLLOW UP:

	2 wks	4wks	6wks	10 wks	3 mths	6mths	1 yr.
ESR							
CRP							
XRAY							

OUTCOME

- No infection / persistent infection
- Union / stable nonunion / unstable nonunion

SUBSEQUENT PROCEDURES

- Exchange nailing(antibiotic cement nail / uncoated interlocking nail) ☐
- Bone grafting ☐
- Plating ☐
- External fixator ☐
- Plastic surgery procedures ☐

COMPLICATIONS

MASTER CHART

S.NO	NAME	AGE (Year)	SEX	BONE	DURATION OF INFECTION (Months)	INITIAL TREATMENT	SUBSEQUENT PROCEDURES	BONE DEFICIT (cms)	DURATION OF FOLLOW UP (Months)	OUTCOME			PALEY'S CRITERIA	
										INFECTION CONTROL	BONY UNION	DEFORMITY	BONY OUTCOME	FUNCTIONAL OUTCOME
1	JAGANMOHAN	60	M	TIBIA	6	DEB. EXT FIX.	NIL	0	8	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
2	KARTHICK	21	M	TIBIA	4	DEB.	NIL	0	6	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
3	NATRAJ	35	M	TIBIA	6	DEB. EXT FIX	FC, BM INJ.	0	12	CONTROLLED	YES	< 7 DEG VARUS	EXCELENT	EXCELLENT
4	RAGHU	24	M	FEMUR	9	IM NAIL	SSG	0	12	CONTROLLED	YES	NIL	EXCELLENT	GOOD
5	NARAYANASAMY	45	M	TIBIA	6	IM NAIL	NIL	0	8	CONTROLLED	YES	< 7 DEG VARUS	EXCELLENT	EXCELLENT
6	MURALIMOHAN	21	M	FEMUR	6	DEB,AK CAST	NIL	1.5	6	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
7	KANDASAMY	45	M	TIBIA	4	DEB, AK CAST	NIL	0	6	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
8	FERNANDEZ	23	M	FEMUR	6	DEB, AK CAST	SSG	1	10	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
9	ANANDAN	38	M	TIBIA	8	DEB. EXT FIX.	EX NAIL	2	14	UNCONTROLLED	NO	> 7 DEG VARUS	POOR	POOR
10	ANNAMALAI	51	M	TIBIA	12	IM NAIL	NIL	1.5	10	CONTROLLED	YES	NIL	EXCELLENT	GOOD
11	SENTHIL	25	M	TIBIA	9	IM NAIL	NIL	1	6	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
12	SARAVANAN	28	M	TIBIA	6	DEB. EXT FIX.	BM INJ	0	10	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
13	DAYALAN	25	M	TIBIA	5	DEB. EXT FIX	EX NAIL, FC	1.5	15	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
14	PANDURANGAN	53	M	FEMUR	24	PLATE, DEB.	EX NAIL	2.5	15	CONTROLLED	YES	YES	FAIR	GOOD
15	KANDASAMY	45	M	TIBIA	12	DEB, EXT FIX.	NIL	0	10	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
16	KULLAVANDU	48	M	TIBIA	6	NIL	NIL	0	9	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
17	KANNAYIRAM	60	M	TIBIA	8	IM NAIL	FC	0	8	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
18	NAGARAJ	25	M	FEMUR	15	PLATE	NIL	2	15	CONTROLLED	YES	NIL	GOOD	GOOD
19	RAJASEKHARAN	38	M	TIBIA	24	PLATE,BG	NIL	1	10	CONTROLLED	YES	NIL	GOOD	EXCELLENT
20	BASKARAN	60	M	TIBIA	15	NATIVE SPLINT	SSG	2	6	CONTROLLED	YES	NIL	EXCELLENT	GOOD
21	GOPALAKRISHNAN	65	M	TIBIA	4	NATIVE SPLINT	NIL	1	8	CONTROLLED	YES	< 7 DEG VARUS	EXCELLENT	EXCELLENT
22	GOVINDAN	58	M	TIBIA	6	IM NAIL	NIL	1	6	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
23	ARJUNAN	46	M	TIBIA	4	AK CAST	SSG	1	9	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
24	JEYACHANDRAN	54	M	TIBIA	4	DEB. EXT FIX	NIL	0	10	CONTROLLED	YES	NIL	EXCELLENT	EXCELLENT
25	KATHIJA	45	F	FEMUR	20	IM NAIL	NIL	2.5	8	CONTROLLED	NO	NIL	POOR	POOR

DEB - Debridement, EXT. FiX. - External Fixator, BG - Bone Grafting, IM - Intramedullary Nail, AK - Above Knee Cast

FC - Flap Cover, BM INJ. - Bone Marrow Injection, SSG - Split Skin Graft, EX. NAIL - Exchange Nailing